

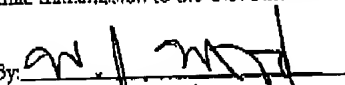
Due Date: September 13, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: William P. Van Antwerp et al. Examiner: David Lukton
Serial No.: 09/733,738 Group Art Unit: 1653
Filed: December 8, 2000 Docket: G&C 130.9-US-U1
Title: MIXED BUFFER SYSTEM FOR STABILIZING POLYPEPTIDE
FORMULATIONS

CERTIFICATE OF MAILING OR TRANSMISSION UNDER 37 CFR 1.8

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By: 
Name: William J. Wood

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated August 13, 2002, please amend the above-identified application as follows:

REMARKSA. Restriction Requirement

The Office Action dated August 13, 2002 required restriction of the claims into four claim Groups. In response, Applicants elect Group 4, namely claims 19-24.

However, Applicants do so with traverse. Applicants dispute the assertion by the Office that the four claim Groups involve separate and distinct inventions.

35 U.S.C. §121 provides that "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." M.P.E.P. §802.01 deviates from the plain meaning of "independent and distinct" by interpreting "and" to mean "or". The Patent Office relies on the absence from the legislative

history of anything contrary to this interpretation as support for their position that "and" means "or". Applicants respectfully note that this position is contrary to the rules of statutory construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

The Examiner does not assert that the inventions of the four claim Groups are independent. Rather, the Examiner alleges that the inventions of the four claim Groups are distinct. According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion has been met in the present case, which it has not, the second criterion has not been met. In this context, Applicants further urge the Examiner take into consideration that the subject matter of each of the claim Groups is linked by a common inventive concept.

Applicants assert that a search into prior art with regard to the invention of the different Groups is so related that separate significant search efforts should not be necessary. Accordingly, there is no serious burden on the Examiner to collectively examine the different claim Groups of the subject application. Therefore, restriction is not proper under M.P.E.P. §803.

Consequently, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement.

B. Election of Species Requirement

The Examiner further requires Applicants to elect various species for prosecution on the merits to which claims shall be restricted if no generic claim is finally held to be allowable. In this context the Examiner further notes that upon allowance of a generic claim, Applicant will be entitled to additional species which are written in dependent form or otherwise include all of the limitations of the allowed generic claim as provided by 37 CFR 1.141.

In response to the Examiner's requirement (a), a specific peptide such as Asp B28 human insulin, Ser-17 human beta-interferon, or bovine interleukin-2, Applicants elect LysB28ProB29-human insulin as taught for example at page 6, lines 27-32. In response to the Examiner's requirement (b), a specific "buffering molecule" which absorbs CO₂ but which lacks a free amine group, Applicants elect phosphate. In response to the Examiner's requirement (c), zinc is present, or zinc is absent, Applicants elect zinc is present. In response to the Examiner's requirement (d), an

isotonicity agent is present or an isotonicity agent is absent, Applicants elect the isotonicity agent is present and a specific agent is glycerol. In response to the Examiner's requirement (e), the election of a specific phenol, Applicants elect phenol (C_6H_5OH). Applicants election of all of the above species is made with traverse.

It is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP
Attorneys for Applicant(s)

Howard Hughes Center
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(310) 641-8797

Date: September 13, 2002

By: 

Name: William J. Wood
Reg. No.: 42,236

WJW/sjm

G&C 130.9-US-U1

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9/Elect**Gates & Cooper** LLPHoward Hughes Center
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GROUP 1600**FAX TRANSMISSION TO USPTO**TO: Commissioner for Patents
Attn: Examiner David Lukton
Patent Examining Corps
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Washington, D.C. 20231FROM: William J. Wood
OUR REF.: G&C 130.9-US-U1
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Applicant:	William P. Van Antwerp et al.
Serial No.:	09/733,738
Filed:	December 8, 2000
Group Art Unit:	1653
Our Ref. No.:	G&C 130.9-US-U1

By: William J. Wood
Name: William J. Wood
Reg. No.: 42,236

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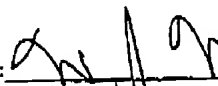
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- ☒ Response to Restriction Requirement.

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A duplicate of this paper is enclosed.

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